

ERN Data Management Strategy Multistakeholder Workshop

Organisers: ERICA WP2 (Franz Schaefer, Clémence Le Cornec)

Scientific programme committee: Franz Schaefer, Clémence Le Cornec, Inés Hernando, Vittoria Carraro, Kristina Larsson and Leo Schultze Kool

Date and time: Heidelberg, 17th – 18th of October 2022 (online if the corona restrictions do not allow the meeting to take place face to face)

Venue: Villa Bosch, Schloß-Wolfsbrunnenweg 33, 69118 Heidelberg.

Description:

This conference is the final of the series of workshops on the ERN data management strategy. This workshop will provide an **opportunity for all stakeholders** – patients, researchers, industry, and regulatory authorities - to make their needs and expectations heard and ensure their consideration in the principles and implementation of a coherent data management strategy by the ERNs.

It is planned to develop a **white paper on a data management strategy for the ERNs** based on the conclusions from the preliminary workshops and seminars and on the discussions held during this final 2-day workshop in Heidelberg.

Final Agenda

17th October (9h00 – 18h00)

9h00 - 9h05	Welcome, aims & objectives of the meeting <i>Franz Schaefer</i>
9h05 – 9h25	<i>Keynote lecture: Innovative use of healthcare data</i> <i>Cécile Ollivier, CPATH</i>
Session 1: Data use by the ERNs: Status update	
9h25 – 9h50	Scope of clinical data use for research by the ERNs (including but not limited to ERN registries) <i>Franz Schaefer</i>
9h50 – 10h15	Current status of ERN registry data: ERNs data dictionary, data collection process, data quality framework <i>EJP RD FAIRification Stewards</i>
Session 2: Stakeholder expectations regarding ERN Registry data	
10h15 – 10h35	ERN researchers' expectations for the use of registry data & vision to share data <i>Holm Graessner and Mar Manu Pereira, ERN coordinators</i>
<i>10h35 – 11h00</i>	<i>Coffee break</i>
11h00 – 11h15	Needs and expectations of industry <i>John Waller, Senior Director for RWE Rare Disease at Novo Nordisk</i>

11h15 – 11h30	Needs and expectations of HTA agencies <i>Yvonne Schmidt, Pharmaceuticals Department, German Federal Joint Committee</i>
11h30 – 11h45	Needs and expectations of European regulatory authorities <i>Carla Jonker, European Medicine Agency</i>
11h45 – 12h00	Needs and expectations of patient community <i>Elizabeth Vroom, Duchenne Parent Project</i>
12h00 – 12h15	Needs and expectations of national and European health authorities <i>Anne-Sophie Lapointe, French Health Ministry</i>
12h15 – 13h00	Plenary discussion: What is needed to align the expectations and collaborate (governance, data sharing aspects ...) <i>All, moderator: Inés Hernando</i>
<i>13h00 – 14h00</i>	<i>Lunch break</i>
Session 3: Structural components of data management	
14h00 – 14h25	Sharing without over-sharing: one approach to being “just open enough” <i>Nawel Lalout, Duchenne Parent project, The Netherlands and Pablo Alarcon on the behalf of Mark Wilkinson, UPM-INIA Universidad Politécnica de Madrid</i>
14h25 – 14h50	Privacy-preserving federated analytics in the framework of the Swiss Personalised Health Network. <i>Jean-Louis Raisaro, Centre Hospitalier Universitaire Vaudois (CHUV)</i>
14h50 – 15h15	EJP RD Virtual Platform: existing and future infrastructure, requirements for data holders and data users. Authentication and authorization management. How will the VP integrate into the CRN of the Rare Disease Partnership? <i>Ana Rath, INSERM</i>
15h15 – 16h00	Plenary discussion: What are the key requirements to collect fit-for-purpose data for the different stakeholders’ identified needs? How to address these requirements? How to make the data findable, accessible, interoperable, and reusable? How to enhance collaboration? <i>All, moderator: Franz Schaefer</i>
<i>16h30 – 17h00</i>	<i>Coffee break</i>
Session 4: Operational aspects to implement an ERN wide data management strategy	
17h00 – 17h45	Implementation of an efficient system of data collection (summary and discussion of Essentials from previous ERICA Workshop). <ul style="list-style-type: none"> - Patient enrolment routines - Choice of data to be collected - Data capture routines - Patient involvement in data collection (patient access to eCRF, role of wearables in rare diseases...) <i>Clémence Le Cornec</i>

18th October (8h30 – 14h15)

8h30 – 9h15	Implementation of a data quality strategy (summary and discussion of Essentials from previous ERICA workshop). <i>Clémence Le Cornec</i>
9h15 – 10h00	Implementation of a data access policy (summary and discussion of Essentials from previous ERICA workshop). - Principles - Governance - Workflow - Future embedding in EJP RD, EHDS <i>Franz Schaefer</i>
<i>10h00 – 10h30</i>	<i>Coffee break</i>
10h30 – 11h00	Use of pseudonymised and anonymised data (summary and discussion of Essentials from previous ERICA workshop). <i>Clémence Le Cornec</i>
11h00 – 12h15	Funding models for the ERN registries: ensuring the short-, medium- and long-term viability of the ERN registries and the reuse of the data collected. The c4c and Together4RareDisease initiative will be presented, followed by an hour discussion on the ERN registries funding models. <i>Vicky Hedley, c4c</i>
12h15 – 13h00	Outline of the white paper and distribution of writing tasks <i>All, moderator: Franz Schaefer</i>
13h00 – 13h15	Conclusion from the workshop <i>Franz Schaefer</i>
<i>13h15 – 14h15</i>	<i>Lunch and end of the workshop</i>